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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/462,629	01/11/00	SEULBERGER	H 48141

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EXAMINER	
KRUSE, D	
ART UNIT	**PAPER NUMBER**
1638	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary	Application No. 09/462,629	Applicant(s) SEULBERGER ET AL.	
	Examiner David H Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-24* is/are pending in the application.

4a) Of the above claim(s) *18-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Claims 1-16 in Paper No. 11, filed 13 June 2001 is acknowledged. The traversal is on the ground(s) that the special technical feature common to Groups I-IV is the invention's reliance on over-expression of an HPPD gene in plants (Reply, page 3). This is not found persuasive because the method of Group I does not claim higher expression (over expression) of an HPPD gene, this characteristic is only claimed in Group IV for producing plants with elevated resistance to HPPD inhibitors. Thus, the special technical feature is deemed the broadly claimed DNA sequence encoding an HPPD enzyme of Claim 1, which was known in the prior art.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 18-24 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

3. This application contains claims 18-24, drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144). See MPEP § 821.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if

one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825. Specifically, on page 18 of the Specification. Applicant must submit a CRF copy and paper copy of the Sequence Listing, a statement that the content of the paper and computer readable copies are the same and where applicable include no new matter as required by 37 C.F.R. § 1.821(e) or 1.821(f) or 1.821(g) or 1.825(d), as well as an amendment directing its entry into the specification.

Failure to comply with these requirements in response to this Office Action will result in ABANDONMENT of the application under 37 CFR § 1.821(g).

Priority

6. Applicant's claim to foreign priority under 35 U.S.C. § 119(a)-(d), is acknowledged. If Applicant wishes to perfect the claimed foreign priority, a certified translation of the German patent application should be submitted in a timely manner in response to this office action.

Specification

7. The format of the Specification is objected to by the Examiner. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) ~~Reference to a "Microfiche Appendix" (see 37 CFR § 1.96).~~
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR §§ 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR § 1.821-1.825).

8. The diagram on page 6 of the Specification is objected to. The diagram should be deleted from the body of the Specification and submitted on a separate page as a proper drawing. In addition, a brief description of the submitted drawings is missing from the body of the Specification. Appropriate correction is required.

Claim Objections

9. Claim 13 is objected to because of the following informalities: The listed species are not in number agreement, *i.e.* "oats" and "sunflowers". Appropriate correction is required.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 1 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claim reads on a product of nature and should read -- The isolated DNA sequence --.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-16 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a DNA sequence encoding a hydroxyphenylpyruvate dioxygenase (HPPD) isolated from barley, an expression vector comprising said isolated DNA sequence, a method of transforming comprising said expression cassette and a plant transformed therewith, does not reasonably provide enablement for other plant DNA sequences encoding an HPPD or uses thereof. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims the (isolated) DNA sequence of SEQ ID NO: 1 encoding an HPPD enzyme, isolated from barley, and DNA sequences hybridizing therewith, an expression cassette comprising said DNA sequence, methods of using said expression cassette and plants transformed therewith having an elevated vitamin E content.

Applicant teaches SEQ ID NO: 1 encoding a barley HPPD enzyme and plants transformed therewith having an elevated vitamin E content (Example 7 on page 27).

Applicant does not teach all other DNA sequences that hybridize to SEQ ID NO: 1,or how to isolate said DNA sequences.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant broadly claims a DNA sequence that hybridizes with SEQ ID NO: 1, which encodes a barley HPPD enzyme. Applicant does not teach how to identify and isolate all of the claimed DNA sequences because Applicant only gives general guidance for Southern blot analysis, used to isolate a genomic clone of the instant invention (page 23 of the Specification). In addition, Applicant admits that "A knowledge

of the HPPD DNA sequence is an absolute prerequisite both...and for increasing the vitamin E synthesis in plants" (page 5 lines 11-14 of the Specification). Hence, it would have required undue trial and error experimentation for one of skill in the art at the time of Applicant's invention to isolate all of the DNA sequences that would "hybridize" to Applicant's SEQ ID NO: 1, identify those that are useful, produce expression cassettes and transform plants, identifying those transformed plants that have elevated vitamin E content.

See *Amgen inc. v Chagai Pharmaceutical co.*, 18 USPQ 2d 1016 (Fed. Cir. 1991), which teaches that the conception of a chemical compound requires the inventor to be able to define the compound so as to distinguish it from other materials, and to describe how to obtain it rather than simply defining it solely by its principle biological property; thus, when an inventor of a gene, which is a chemical compound albeit a complex one, is unable to envision detailed constitution of the gene so as to distinguish it from other materials, as well as a method of obtaining it, the conception is not achieved until a reduction to practice has occurred, and until after the gene has been isolated.

14. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

15. Claims 2-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 2 line 1, the phrase "a DNA" should read -- the DNA --. In addition, the claim is indefinite because it is unclear who the promoter and DNA are associated. It is suggested that the claim read -- a promoter operably lined to the DNA --.

At Claims 3 and 4, the phrase "the...promoter" lacks proper antecedent basis and should read -- a...promoter --.

At Claims 3-5, the phrase "An expression cassette" should read -- The expression cassette --.

Claim 5 is indefinite because it is unclear how Applicant is further limiting Claim 2, the wording -- claim 2, further comprising the DNA -- is suggested. In addition, at line 3, the phrase "another protein" is indefinite because Applicant is further limiting a DNA sequence, the claim should read -- another DNA sequence encoding a protein --.

At Claim 7 line 2, the phrase "an expression cassette" should read -- the expression cassette --.

At Claim 8 line 5, the phrase "using the latter for transforming plants" is not a positive method step and thus renders that method indefinite. The phrase -- transforming a plant with the isolated recombinant clones -- is recommended.

At Claim 9 line 1, the phrase "the transformation" lacks proper antecedent basis because claim 8 does not comprise a transforming step. The phrase -- the method -- is suggested.

At Claims 9-11, 15 and 16, the phrase "A method" should read -- The method --.

At Claims 10 and 11, line 2, the phrase "the transformation" lacks proper antecedent basis and should read -- the introducing step --.

At Claim 12, the phrase "an expression cassette" should read -- the expression cassette --.

At Claim 13, the phrase "A plant" should read -- The plant --. In addition, the claim is in improper Markush format, at line 3 the phrase "or sunflowers" should read – and sunflowers --.

At Claim 14 line 2, the phrase "a DNA" should read -- the DNA --.

16. Claim 6 provides for the use of the expression cassette of claim 2, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 6 is rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

18. Claim 1 is rejected under 35 U.S.C. § 102(a) as being anticipated by Krupinska *et al* (Genbank disclosure, Accession # AJ00693, 16 December 1997).

Krupinska disclose the DNA sequence of SEQ ID NO: 1.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

19. Claims 1-3, 5-12, 14 and 16 are rejected under 35 U.S.C. § 102(e) as being anticipated by DellaPenna *et al* (U.S. Patent 6,087,563).

DellaPenna discloses an isolated DNA sequence from *Arabidopsis* that would "hybridize" to Applicant's SEQ ID NO: 1, encoding an HPPD enzyme (Claim 1). DellaPenna discloses an expression cassette comprising said isolated DNA sequence at claim 3, use of the CaMV 35S promoter at column 13 line 49, and *Agrobacterium*, particle bombardment and electroporation transformation methods at column 7 lines 51-55. DellaPenna discloses an expression cassette comprising a chimeric gene at column 6 lines 51-55. DellaPenna inherently discloses a method of transforming a plant cell, callus tissue, entire plant or plant cell protoplast. Finally, DellaPenna discloses a plant with elevated vitamin E content comprising the disclosed expression cassette wherein the expression takes place in the leaves or the seeds at column 4 lines 14-16. Hence, all of the claim limitations have been previously disclosed by DellaPenna.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 4, 13 and 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over DellaPenna *et al* (U.S. Patent 6,087,563) in view of Applicant's admission.

The teachings of DellaPenna are discussed above.

DellaPenna does not teach an expression cassette comprising the seed-specific phaseolin promoter or transformed soya, barley, oat, wheat, oilseed rape, maize, tobacco, or sunflower.

Applicant admits that the seed-specific phaseolin promoter was known in the art at the time of the instant invention (page 9, line18 of the Specification).

Hence, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of Applicant's invention to use a known seed-specific promoter to modify the teachings of DellaPenna. In addition, the claimed transformed plants of Claims 13 and 15 would have been considered functional equivalents to the tomato or *Arabidopsis* taught by DellaPenna.

Conclusion

22. No claims are allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Paula Hutzell can be reached at (703) 308-4310. The fax telephone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3482.

Amy Nelson

AMY J. NELSON, PH.D
PRIMARY EXAMINER

David H. Kruse, Ph.D.
24 August 2001